IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 07-CV-00694 WYD-MJW

DAVID R. DUNN,

Plaintiff,

v.

PFIZER, INC.,
PHARMACIA CORPORATION,
MONSANTO COMPANY, AND
G.D. SEARLE & COMPANY,

Defendants,

ANSWER TO PLAINTIFF'S COMPLAINT AND JURY DEMAND

COME NOW Defendants, Pfizer Inc. ("Pfizer" improperly captions as "Pfizer, Inc."), Pharmacia Corporation ("Pharmacia" and improperly captioned as "Monsanto Company"), and G. D. Searle LLC ("Searle" improperly captioned as G.D. Searle & Company") (collectively "Defendants"), and hereby answer Plaintiff's Complaint in this action and state as follows:

PRELIMINARY STATEMENT

In December 1998, Celebrex® was approved, as labeled, by the United States Food and Drug Administration ("FDA") as a prescription medication. Searle developed, tested, and co-promoted Celebrex® in the United States to be prescribed for the indications set forth in its FDA-approved package insert and as permitted by law. Celebrex® was manufactured and packaged for Searle. Prior to April 2003, Pfizer co-promoted Celebrex® in the United States.

In April 2003, Pfizer merged with Pharmacia and the responsibilities for Celebrex® were reallocated. Celebrex® is presently advertised, promoted, marketed and distributed in the United States by Defendants or one of their subsidiaries to be prescribed by healthcare providers who are authorized by law to prescribe medication in accordance with their approval by the FDA.

The Complaint does not state when Plaintiff was prescribed or used Celebrex®, and as such, this Answer can only be drafted generally and without reference to a specific period in time. Defendants reserve the right to amend this Answer if or when discovery reveals the time period in which Plaintiff was prescribed and used Celebrex®.

This preliminary statement is incorporated by reference in its entirety in response to each and every paragraph of Plaintiff's Complaint.

ANSWERING:
I.

1. Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph.

ANSWERING:
II.
PARTIES

2. Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph.

3. Searle developed, tested, and co-promoted Celebrex® in the United States to be prescribed for the indications set forth in its FDA-approved package insert and as permitted by law. Celebrex® was manufactured and packaged for Searle. Prior to April 2003, Pfizer co-promoted Celebrex® in the United States. In April 2003, Pfizer merged with Pharmacia and the responsibilities for Celebrex® were reallocated. Defendants

admit that Pharmacia has marketed Celebrex® at certain times and that Pfizer has marketed and co-promoted Celebrex® at certain times in the United States to be prescribed for the indications set forth in its FDA-approved package insert and as permitted by law. Celebrex® is presently advertised, promoted, marketed and distributed in the United States by Defendants or one of their subsidiaries to be prescribed by healthcare providers who are authorized by law to prescribe medication in accordance with their approval by the FDA. Defendants state that Plaintiff's allegation regarding place of service is a legal conclusion to which no response is required. Defendants deny the remaining allegations contained in this Paragraph.

4. Defendants admit that Pharmacia is a corporation existing under the laws of the State of Delaware with its principal place of business in the State of New Jersey and is registered to do business in Colorado. Defendants state that Plaintiff has not provided sufficient information for Defendants to form a belief as to the meaning of "at all times relevant." Searle developed, tested, and co-promoted Celebrex® in the United States to be prescribed for the indications set forth in its FDA-approved package insert and as permitted by law. Celebrex® was manufactured and packaged for Searle. Prior to April 2003, Pfizer co-promoted Celebrex® in the United States. In April 2003, Pfizer merged with Pharmacia and the responsibilities for Celebrex® were reallocated. Defendants admit that Pharmacia has marketed Celebrex® at certain in the United States to be prescribed for the indications set forth in its FDA-approved package insert and as permitted by law. Except as admitted herein, Defendants deny the remaining allegations contained in this Paragraph.

5. Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc., and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has never manufactured, marketed, sold or distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of Pharmacia. As the 2000 Monsanto does not and has never manufactured, marketed, sold or distributed Celebrex®, Defendants are therefore stating that the 2000 Monsanto is not a proper party in this matter. Except as specifically admitted herein, Defendants deny the allegations in this Paragraph.

6. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York and is registered to do business in Colorado. Defendants admit that during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in its FDA-approved package insert and as permitted by law. Defendants state that Plaintiff has not provided sufficient information for Defendants to form a belief as to the meaning of "the relevant time period." Except as specifically admitted herein, Defendants deny the remaining allegations in this Paragraph.

7. Defendants admit that Searle is a wholly-owned subsidiary of Pharmacia Corporation, which is in turn a wholly-owned subsidiary of Pfizer. Searle is a Delaware

limited liability company with its principal place of business in Illinois and is registered to do business in Colorado. Defendants state that Plaintiff has not provided sufficient information for Defendants to form a belief as to the meaning of "at all times relevant." Searle developed, tested, and co-promoted Celebrex® in the United States to be prescribed for the indications set forth in its FDA-approved package insert and as permitted by law. Celebrex® was manufactured and packaged for Searle. Except as admitted herein, Defendants deny the remaining allegations contained in this Paragraph.

ANSWERING:
III.
JURISDICTION AND VENUE

8. Defendants admit the allegations contained in this Paragraph.

9. Defendants state that this Plaintiff's statements regarding venue are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations contained in this Paragraph. Defendants deny that they made material omissions and misrepresentations and breaches of warranties. Defendants deny the remaining allegations contained in this Paragraph.

10. Defendants state that the allegations in this Paragraph are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations contained in this Paragraph.

ANSWER:
IV.
FACTUAL ALLEGATIONS

11. Searle developed, tested, and co-promoted Celebrex® in the United States, including in the State of Colorado, to be prescribed for the indications set forth in its FDA-approved package insert and as permitted by law. Celebrex® was manufactured

and packaged for Searle. Prior to April 2003, Pfizer co-promoted Celebrex® in the United States. In April 2003, Pfizer merged with Pharmacia and the responsibilities for Celebrex® were reallocated. Defendants admit that Pharmacia has marketed Celebrex® at certain times and that Pfizer has marketed and co-promoted Celebrex® at certain times in the United States, including in the State of Colorado, to be prescribed for the indications set forth in its FDA-approved package insert and as permitted by law. Celebrex® is presently advertised, promoted, marketed and distributed in the United States, including in the State of Colorado, by Defendants or one of their subsidiaries to be prescribed by healthcare providers who are authorized by law to prescribe medications in accordance with their approval by the FDA.

12. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations regarding Plaintiff and her alleged injuries, and therefore deny the same. Defendants deny the remaining allegations contained in this Paragraph.

13. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations regarding Plaintiff and therefore, deny the same. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants also state that the potential effects of Celebrex® were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations contained in this Paragraph.

14. Searle developed, tested, and co-promoted Celebrex® in the United States, including in the State of Colorado, to be prescribed for the indications set forth in its

FDA-approved package insert and as permitted by law. Celebrex® was manufactured and packaged for Searle. Prior to April 2003, Pfizer co-promoted Celebrex® in the United States. In April 2003, Pfizer merged with Pharmacia and the responsibilities for Celebrex® were reallocated. Defendants admit that Pharmacia has marketed Celebrex® at certain times and that Pfizer has marketed and co-promoted Celebrex® at certain times in the United States, including in the State of Colorado, to be prescribed for the indications set forth in its FDA-approved package insert and as permitted by law. Celebrex® is presently advertised, promoted, marketed and distributed in the United States, including in the State of Colorado, by Defendants or one of their subsidiaries to be prescribed by healthcare providers who are authorized by law to prescribe medications in accordance with their approval by the FDA. Except as admitted herein, Defendants deny the allegations contained in this Paragraph.

ANSWERING:

B. Development of Celebrex®

15. Defendants state that Celebrex® is a selective COX-2 inhibitor, which is a class of drugs that are, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants deny the remaining allegations contained in this Paragraph.

16. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxynegnase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme." Defendants deny the remaining allegations contained in this Paragraph.

17. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxynegnase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme." Plaintiff fails to provide the proper context for the remaining allegations in this Paragraph and therefore, Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations, and therefore, deny the remaining allegations contained in this Paragraph.

18. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxynegnase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme." Plaintiff fails to provide the proper context for the remaining allegations in this Paragraph and therefore, Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations, and therefore, deny the remaining allegations contained in this Paragraph.

19. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxynegnase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme." Plaintiff fails to provide the proper context for the remaining allegations in this Paragraph and therefore, Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations, and therefore, deny the remaining allegations contained in this Paragraph.

20. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of

cyclooxynegnase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme." Plaintiff fails to provide the proper context for the remaining allegations in this Paragraph and therefore, Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations, and therefore, deny the remaining allegations contained in this Paragraph.

21. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxynegnase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme." Plaintiff fails to provide the proper context for the remaining allegations in this Paragraph and therefore, Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations, and therefore, deny the remaining allegations contained in this Paragraph.

22. The allegations contained in this Paragraph are not directed at Defendants, and therefore no answer is required.

23. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxynegnase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme." Plaintiff fails to provide the proper context for the remaining allegations in this Paragraph and therefore, Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations, and therefore, deny the remaining allegations contained in this Paragraph. Defendants deny intentionally ignoring or recklessly disregarding current medical knowledge. Defendants deny the remaining allegations contained in this Paragraph.

24. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxynegnase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme." Plaintiff fails to provide the proper context for the remaining allegations in this Paragraph and therefore, Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations, and therefore, deny the remaining allegations contained in this Paragraph. Defendants further state that the results of the referenced Phase I, II, and II trials speak for themselves and deny any characterization of them.

ANSWERING:

C. The CLASS Study

25. Defendants deny the allegations contained in this Paragraph.

26. Defendants deny the allegations contained in this Paragraph.

27. Defendants state that the referenced Celecoxib Long-Term Arthritis Safety Study ("CLASS") speaks for itself and deny any characterization of it. Defendants deny the remaining allegations contained in this Paragraph.

28. Defendants state that the referenced CLASS study speaks for itself and deny any characterization of it.

29. Defendants state that the referenced CLASS study speaks for itself and deny any characterization of it. Defendants deny the remaining allegations contained in this Paragraph.

30. Defendants admit that the results of the CLASS study were submitted to the U.S. Food and Drug Administration ("FDA"), which speaks for itself and any attempt

to characterize it is denied. Defendants deny the remaining allegations contained in this Paragraph.

31. Defendants admit that the Medical Officer Review dated September 20, 2000, was completed by the FDA. Defendants assert that the Medical Officer Review speaks for itself and any attempt to characterize it is denied. Defendants respectfully refer the court to the transcript of the FDA's Arthritis Advisory Committee meeting on February 7 and 8, 2001, which speaks for itself, and any attempt to characterize it is denied. Except as admitted herein, Defendants deny the remaining allegations contained in this Paragraph.

32. Defendants state that the referenced CLASS study speaks for itself and deny any characterization of it. Defendants respectfully refer the court to the transcript of the FDA's Arthritis Advisory Committee meeting on February 7 and 8, 2001, which speaks for itself, and any attempt to characterize it is denied. Defendants deny the remaining allegations contained in this Paragraph.

33. Plaintiff fails to provide the proper context for the allegations contained in this Paragraph and therefore, Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations, and therefore, deny the same.

34. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny making any intentional omissions. Defendants deny the remaining allegations contained in this Paragraph.

35. Defendants admit that a New Drug Application ("NDA") was submitted in June of 1998 to the FDA for the approval of Celebrex®. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied.

36. Defendants admit that an NDA was submitted in June of 1998 to the FDA for the approval of Celebrex®. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied. As indicated in the package insert approved by the FDA, Defendants state that in December 1998, the FDA granted approval for Celebrex®. Celebrex® has been approved for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in juveniles and adults; (3) for relief of the signs and symptoms of ankylosing spondylitis; (4) for management of acute pain in adults; (5) for treatment of primary dysmenorrhea; and (6) to reduce the number of adenomatous colorectal polyps in patients with familiar adenomatous polyposis ("FAP"), as an adjunct to usual care (e.g. endoscopic surveillance, surgery). Except as admitted herein, Defendants deny the remaining allegations contained in this Paragraph.

37. Plaintiff fails to provide proper context for the allegations concerning "intensive marketing campaigns" contained in this Paragraph, and therefore, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations and deny the same. Defendants admit that in 2004, Celebrex® sales exceeded $2 billion. Except as admitted herein, Defendants deny the allegations contained in this Paragraph.

38. Defendants admit that they released the results of the CLASS study, which speaks for itself and any attempt characterize it is denied. Defendants admit that the

results of the CLASS study were published in the Journal of the American Medical Association, which speaks for itself and any attempt to characterize it is denied. Plaintiff's allegations regarding FDA requirements are not directed at Defendants, and therefore, no answer is required. Defendants deny the remaining allegations contained in this Paragraph.

39. Defendants state that the referenced CLASS study speaks for itself and deny any characterization of it. The referenced article in the Journal of the American Medical Association speaks for itself and any attempt to characterize it is denied. Defendants deny the remaining allegations contained in this Paragraph.

40. Defendants state that the referenced CLASS study speaks for itself and deny any characterization of it. The referenced article in the Journal of the American Medical Association speaks for itself and any attempt to characterize it is denied. Defendants deny the remaining allegations contained in this Paragraph.

41. Defendants state that the referenced CLASS study speaks for itself and deny any characterization of it. Defendants admit that a supplemental NDA ("sNDA") was submitted on June 12, 2000, to the FDA for Celebrex®, which speaks for itself and any attempt to characterize it is denied. The referenced Medical Officer Review dated September 20, 2000, completed by the FDA for the sNDA submitted for Celebrex® speaks for itself and any attempt to characterize it is denied. Defendants deny the remaining allegations contained in this Paragraph.

42. The referenced Medical Officer Review completed by the FDA for the sNDA submitted for Celebrex® speaks for itself and any attempt to characterize it is denied. The referenced article in the Journal of the American Medical Association

speaks for itself and any attempt to characterize it is denied. Defendants deny the remaining allegations contained in this Paragraph.

43. Defendants state that the referenced CLASS study speaks for itself and deny any characterization of it. Defendants admit that a supplemental NDA ("sNDA") was submitted on June 12, 2000, to the FDA for Celebrex®, which speaks for itself and any attempt to characterize it is denied. The referenced Medical Officer Review completed by the FDA for the sNDA submitted for Celebrex® speaks for itself and any attempt to characterize it is denied. The referenced article in the Journal of the American Medical Association speaks for itself and any attempt to characterize it is denied. Defendants deny the remaining allegations contained in this Paragraph.

44. Defendants state that the referenced CLASS study speaks for itself and deny any characterization of it. The referenced article in the Journal of the American Medical Association speaks for itself and any attempt to characterize it is denied. Defendants admit that a supplemental NDA ("sNDA") was submitted on June 12, 2000, to the FDA for Celebrex®, which speaks for itself and any attempt to characterize it is denied. The referenced Medical Officer Review completed by the FDA for the sNDA submitted for Celebrex® speaks for itself and any attempt to characterize it is denied. Defendants deny the remaining allegations contained in this Paragraph.

45. Defendants state that the referenced CLASS study speaks for itself and deny any characterization of it. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations contained in this Paragraph.

46. Defendants admit that a letter was issued by the FDA in February of 2001, which speaks for itself, and any attempt to characterize it is denied. Defendants deny the remaining allegations contained in this Paragraph.

47. Defendants admit that a letter was issued by the FDA in February of 2001, which speaks for itself, and any attempt to characterize it is denied. Defendants admit that the "Dear Healthcare Provider" letter was sent, which speaks for itself and any attempt to characterize it is denied. The referenced article in the Journal of the American Medical Association speaks for itself and any attempt to characterize it is denied. Defendants lack sufficient knowledge or information as to form a belief as to the truth of Plaintiff's allegations regarding "doctors" contained in this Paragraph, and therefore, deny the same. Defendants deny the remaining allegations contained in this Paragraph.

ANSWERING:

D. Marketing and Promotion

48. Defendants deny the allegations contained in this Paragraph.

49. Plaintiff fails to provide proper context for the allegations concerning "historic levels" and therefore, Defendants are without sufficient information to form a belief as to the truth of the allegations contained in this Paragraph and deny the same. Defendants deny the remaining allegations contained in this Paragraph.

50. Plaintiff fails to provide proper context for the allegations concerning "blitzed" and therefore, Defendants are without sufficient information to form a belief as to the truth of the allegations contained in this Paragraph and deny the same. Defendants state that, as indicated in the package insert approved by the FDA, in December 1998, the FDA granted approval for Celebrex®. Celebrex® has been approved for the following

indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in juveniles and adults; (3) for relief of the signs and symptoms of ankylosing spondylitis; (4) for management of acute pain in adults; (5) for treatment of primary dysmenorrhea; and (6) to reduce the number of adenomatous colorectal polyps in patients with familial adenomatous polyposis ("FAP"), as an adjunct to usual care (e.g. endoscopic surveillance, surgery). Defendants also state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Defendants deny the remaining allegations contained in this Paragraph.

51. The allegations contained in this Paragraph are not directed at Defendants and therefore no response is required. To the extent a response is required, Defendants deny the allegations contained in this Paragraph.

52. The allegations contained in this Paragraph are not directed at Defendants and therefore no response is required. To the extent a response is required, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph and therefore, deny the same.

53. Defendants deny engaging in any "misleading advertising campaigns." Defendants deny the remaining allegations contained in this Paragraph.

ANSWERING:

E. Risks Posed by Celebrex®

54. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all

times adequate and comported with applicable standards of care and law. Defendants deny the allegations contained in this Paragraph.

55. The allegations contained in this Paragraph are not directed at Defendants and therefore no response is required. To the extent a response is required, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph and therefore, deny the same.

56. Plaintiff fails to provide proper context for the allegations contained in this Paragraph and therefore, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph and therefore, deny the same.

57. Plaintiff fails to provide proper context for the allegations contained in this Paragraph and therefore, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph and therefore, deny the same.

58. The referenced publication from the Cleveland Clinic speaks for itself and any attempt to characterize it is denied.

59. Plaintiff fails to provide proper context for the allegations contained in this Paragraph and therefore, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph and therefore, deny the same.

60. Defendants deny issuing uniformly misleading advertisements and promotional materials. Defendants state that Celebrex® is safe and effective when used

in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations contained in this Paragraph.

61. Defendants deny making deceptive and illegal statements. Plaintiff fails to provide proper context for the allegations contained in this Paragraph and therefore, Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph and therefore, deny the same.

62. Defendants admit that a letter was issued by the Division of Drug Marketing, Advertising and Communications (DDMAC) in October 1999 which speaks for itself, and any attempt to characterize it is denied. Defendants deny making misrepresentations about the safety profile of Celebrex®. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Except as admitted herein, Defendants deny the remaining allegations in this Paragraph.

63. Defendants admit that a letter was issued by the Division of Drug Marketing, Advertising and Communications (DDMAC) in April of 2000 which speaks for itself, and any attempt to characterize it is denied. Defendants deny making misrepresentations about the safety profile of Celebrex®. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Except as admitted herein, Defendants deny the remaining allegations in this Paragraph.

64. Defendants admit that a letter was issued by the Division of Drug Marketing, Advertising and Communications (DDMAC) in February 2001 which speaks

for itself, and any attempt to characterize it is denied. Except as admitted herein, Defendants deny the remaining allegations in this Paragraph.

65. Defendants admit that a "Dear Doctor" letter was sent, which speaks for itself and any attempt to characterize it is denied. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations contained in this Paragraph.

66. Defendants admit that a "Dear Patient" letter was sent, which speaks for itself and any attempt to characterize it is denied. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations contained in this Paragraph.

ANSWERING:

F. Misleading Promotion and Advertising

67. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants also state that the Celebrex® advertising and packaging materials speak for themselves and any attempt to characterize them is denied. Defendants deny the allegations contained in this Paragraph.

68. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants also state that the Celebrex® advertising and packaging materials speak for themselves

and any attempt to characterize them is denied. Defendants deny the allegations contained in this Paragraph.

69. Defendants deny that their advertising and packaging materials for Celebrex® are uniformly fraudulent and misleading. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants also state that the Celebrex® advertising and packaging materials speak for themselves and any attempt to characterize them is denied. Defendants deny the allegations contained in this Paragraph.

70. The referenced print advertisements speak for themselves and any attempt to characterize them is denied.

71. The referenced print advertisements speak for themselves and any attempt to characterize them is denied.

72. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants also state that the referenced print advertisements speak for themselves and attempt to characterize them is denied. Defendants deny the remaining allegations contained in this Paragraph.

ANSWERING:
V.
STRICT PRODUCTS LIABILITY

73. Defendants incorporate their responses to each Paragraph of Plaintiff's Complaint as if set forth fully herein.

74. Defendants deny that the Celebrex® was or is defective and unreasonably dangerous. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations contained in this Paragraph.

75. Defendants deny the allegations contained in this Paragraph.

76. Defendants deny the allegations contained in this Paragraph.

77. Defendants deny the allegations contained in this Paragraph.

78. Defendants deny the allegations contained in this Paragraph.

79. Defendants deny the allegations contained in this Paragraph.

80. Defendants deny the allegations contained in this Paragraph and deny that Plaintiff suffered injuries and monetary damages.

ANSWERING:
VI.
FRAUD

81. Defendants incorporate their responses to each Paragraph of Plaintiff's Complaint as if set forth fully herein.

82. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations concerning Plaintiff, and therefore, deny the same. Defendants deny that they made fraudulent representations. Defendants deny that Plaintiff suffered injuries and monetary damages. Defendants deny the remaining allegations contained in this Paragraph.

ANSWERING:
VII.
NEGLIGENCE

83. Defendants incorporate their responses to each Paragraph of Plaintiff's Complaint as if set forth fully herein.

84. Plaintiff's allegations concerning "sellers and merchants" are legal in nature and therefore, no response is required. To the extent a response is required, Defendants deny the allegations. Defendants admit that they had duties as are imposed by law. Defendants deny that they breached any such duties. Defendants deny the remaining allegations contained in this Paragraph.

85. Defendants deny the allegations contained in this Paragraph.

86. Defendants admit that they had duties as are imposed by law. Defendants deny that they breached any such duties. Defendants deny that Plaintiff sustained any injuries. Except as admitted herein, Defendants deny the remaining allegations contained in this Paragraph.

ANSWERING:
VIII.
NEGLIGENT MISREPRESENTATIONS

87. Defendants incorporate their responses to each Paragraph of Plaintiff's Complaint as if set forth fully herein.

88. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations contained in this Paragraph.

89. Defendants deny making any misrepresentations. Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations

concerning Plaintiff and Plaintiff's healthcare provider and therefore, deny the same. Defendants deny the allegations contained in this Paragraph, including all of its subpart. Defendants deny that Plaintiff sustained any injuries or monetary losses.

ANSWERING:
IX.
EXPRESSED WARRANTY FOR GOODS

90. Defendants incorporate their responses to each Paragraph of Plaintiff's Complaint as if set forth fully herein.

91. Plaintiff's allegations concerning "sellers and merchants" are legal in nature and therefore, no response is required. To the extent a response is required, Defendants deny the allegations. Defendants admit that they had duties as are imposed by law. Defendants deny that they breached any such duties. Except as admitted herein, Defendants deny the remaining allegations contained in this Paragraph. Defendants also deny that Plaintiff sustained any injuries or monetary loss.

ANSWERING:
X.
IMPLIED WARRANTIES

A. WARRANTY OF MERCHATABLITY

92. Defendants incorporate their responses to each Paragraph of Plaintiff's Complaint as if set forth fully herein.

93. Plaintiff's allegations concerning "sellers and merchants" are legal in nature and therefore, no response is required. To the extent a response is required, Defendants deny the allegations. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants

deny the remaining allegations contained in this Paragraph. Defendants also deny that Plaintiff sustained any injuries or monetary loss.

ANSWERING:

B. WARRANTY OF FITNESS

94. Defendants incorporate their responses to each Paragraph of Plaintiff's Complaint as if set forth fully herein.

95. Defendants state that Celebrex® is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants are without sufficient information or knowledge to form a belief as to the truth of the allegations concerning Plaintiff and Plaintiff's healthcare provider and therefore, deny the same. Defendants deny the remaining allegations contained in this Paragraph. Defendants also deny that Plaintiff sustained any injuries or monetary loss.

ANSWERING:

XI.

DAMAGES

96. Defendants deny that Plaintiff sustained serious injuries and damages as a proximate result of Defendants' conduct. Defendants deny the remaining allegations contained in this Paragraph.

ANSWERING:

XII.

PUNITIVE DAMAGES

97. Defendants deny that their actions were a result of fraud, ill will, recklessness, and/or willful and intentional disregard for the safety and right of Plaintiff, as well as the general public and/or consumer of the Celebrex® drug. Defendants deny

the remaining allegations contained in this Paragraph. Defendants also deny that Plaintiff is entitled to punitive damages.

ANSWERING:
XIII.
JURY DEMAND

98. Defendants demand a trial by jury on all issues so triable.

ANSWERING:
XIV.
PRAYER

Defendants deny that Plaintiff is entitled to any of the relief demanded in the unnumbered WHEREFORE clause, including its subparts.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Defendants in this matter. Defendants therefore assert the following defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Defendants will withdraw any of these defenses as may be appropriate.

1. Plaintiff's Complaint fails to state a claim against Defendants upon which relief can be granted.

2. Plaintiff's claims are barred by the applicable statute of limitations and/or repose or by the equitable doctrines of laches, waiver and estoppel.

3. Plaintiff's injuries and damages, if any, were solely caused by the acts or omissions, abuse or misuse, negligence or fault or otherwise, of third persons or parties over whom Defendants had no control or right to control and whose actions are not, therefore, imputable to Defendants.

4. Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff herein. Additionally, as a manufacturer and not a seller, Defendants are not subject to liability for implied warranties without privity, i.e., proof of direct and specific transactions between Plaintiff and Defendants. If any such warranties were made, whether express or implied, which Defendants specifically deny, then Plaintiff failed to give timely notice of any breach thereof as required under Colo. Rev. Stat. Ann. § 4-2-607(3)(a).

5. Plaintiff's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff or those acting at the direction or control of Plaintiff, whose contributory negligence or fault is sufficient to bar any recovery by Plaintiff.

6. Plaintiff's injuries, if any, were due to an unforeseeable idiosyncratic reaction of Plaintiff, or by an unforeseeable disease or illness, unavoidable accident, or pre-existing and/or unrelated conditions, or natural courses of conditions of Plaintiff, and were independent of any conduct by Defendants.

7. Plaintiff failed to exercise reasonable care and diligence to mitigate injuries and damages, if any.

8. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

9. Celebrex® is safe when used as directed, was suitable for the purpose for which it was intended, was distributed with adequate and sufficient warnings and Defendants reasonably assumed that its warnings would be read and heeded; therefore,

Celebrex® is neither defective nor unreasonably dangerous pursuant to Restatement (Second) of Torts § 402A, Comment j.

10. As a prescription pharmaceutical, Celebrex® falls within the ambit of the Food, Drug and Cosmetic Act and regulations promulgated by the Food and Drug Administration. Accordingly, Plaintiff's claims have been preempted under the Supremacy Clause of the U.S. Constitution.

11. Celebrex® and Defendants' actions conformed to the state-of-the-art of medical and scientific knowledge at all times relevant to this lawsuit and Celebrex® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

12. Plaintiff's claims are barred by assumption of the risk.

13. Plaintiff's claims are barred in whole or in part because Celebrex® "provides net benefits for a class of patients" within the meaning of the Restatement (Third) of Torts: Product Liability § 6, comment f.

14. Plaintiff's claims asserted in the Complaint are barred in whole or in part by the "learned intermediary" doctrine.

15. The imposition of punitive damages pursuant to current Colorado law violates the Due Process and Equal Protection provisions of U.S. Const. Amend. XIV; to wit, these Defendants have not been given fair notice of the standard of conduct which could subject them to a claim for punitive damages, and have not been given fair notice of the amount of punitive damages that may accompany a finding of liability. Colorado's current laws regarding punitive damages do not serve a rational or legitimate state interest.

16. Plaintiff's claims for punitive damages violate these Defendants' rights under the Fifth, Sixth, Seventh, Eighth, and Fourteenth Amendment of the Constitution of the United States of America and Article 1, Sections 1, 2, 6, 11, 13, 15, 27, and 35 of the Constitution of Colorado.

17. Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damages awards which arise under the United States Constitution and decisions of the United States Supreme Court including, but not limited to: *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003). Further, Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damages, which arise under the Constitution of Colorado, Colorado state statutes, and the decisions of Colorado state courts.

18. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

19. Plaintiff's claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale. Col. Rev. Stat. Ann. §13-21-403(1)(b).

20. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by operation of nature or other

supervening or intervening conduct of persons other than Defendants, and for whose conduct Defendants are not responsible, or with whom Defendants have no legal relation or legal duty to control.

21. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by the unforeseeable alterations, improper handling, or other unforeseeable misuse of Celebrex® by persons other than Defendants or persons acting on their behalf.

22. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

23. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

24. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

25. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of Celebrex® complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

26. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to Celebrex® were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

27. Plaintiff's claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

28. Plaintiff's claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

29. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure.

30. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

31. The liability of Defendants, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimant and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

32. Defendants are entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiff with any other Defendants or other person or entity.

33. Plaintiff's claims are preempted by federal law and regulations, including but not limited to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §301 *et. seq.*, the regulations promulgated hereunder, and the United States Constitution, Article IV, clause 2.

34. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

35. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.

36. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated hereunder, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

37. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

38. Plaintiff's claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

39. Plaintiff's claims are barred or limited in accordance with Colo. Rev. Stat. §§ 13-21-401 through 13-21-406 and Colo. Rev. Stat. §§ 13-21-102, 102.5, 111.5, 111.6, and 111.7.

WHEREFORE, Defendants respectfully requests that this matter be dismissed with prejudice and that they be awarded their costs and any other relief to which they may be entitled.

Respectfully submitted this 26th day of April, 2007.

/s/K. Michele Anderson
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CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of April 2007, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following e-mail addresses:

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